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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98 D-0785]

Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of guidance; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending until April 14, 1999, the comment period for the draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologic." FDA published a notice of availability of the draft guidance in the **Federal Register** of October 14, 1998 (63 FR 55067). FDA is taking this action in response to requests for an extension.

DATES: Written comments on the draft guidance may be submitted by April 14, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-2 10), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration,

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5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert K. Leedham, Jr., Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3500, or George Q. Mills, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5097.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." The draft guidance is intended to assist developers of drug and biological products used for medical imaging, as well as radiopharmaceutical drugs used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance also provides information on how the agency would interpret and apply provisions in proposed regulations, published in the **Federal Register** of May 22, 1998 (63 FR 28301), for in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The draft guidance applies to medical imaging drugs that are used for diagnosis and monitoring and that are administered in vivo. The draft guidance is not intended to apply to possible therapeutic uses of these drugs or to in vitro diagnostic products. Interested persons were given until December 14, 1998, to submit written comments on the draft guidance.

In a notice published in the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened the comment period on the draft guidance until February 12, 1999.

At a January 25, 1999, public meeting on the draft guidance requested by the Council on Radionuclides and Radiopharmaceuticals (CORAR), a representative of Bracco Diagnostics Inc. (Bracco) requested that FDA extend the comment period on the draft guidance to allow manufacturers of contrast media to attempt to reach consensus and submit comments on the draft

guidance. On January 27, 1999, FDA received letters from Bracco and from CO RAR's legal counsel requesting that the agency extend the comment period.

In response to these requests, FDA has decided to extend the comment period on the draft guidance until April 14, 1999, to allow the public more time to review and comment on its contents. FDA also intends to hold another public meeting to discuss the draft guidance prior to the close of the comment period.

Interested persons may, on or before April 14, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy, Comments should

be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 1999

William K. Hubbard
Associate Commissioner
for Policy Coordination

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